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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-----------------------|------------------|
| 09/785,548 | 02/20/2001 | Hana Koutnikova | ST00005 | 5202 |
| 29693 | 7590 | 11/18/2004 | EXAMINER | |
| WILEY, REIN & FIELDING, LLP ATTN: PATENT ADMINISTRATION 1776 K. STREET N.W. WASHINGTON, DC 20006 | | | HAYES, ROBERT CLINTON | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1647 | |

DATE MAILED: 11/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/785,548

Applicant(s)

KOUTNIKOVA ET AL.

Examiner

Robert C. Hayes, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 30 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32,33,38,39,53,59 and 63-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 39 is/are allowed.
- 6) ☒ Claim(s) 32,33,38,53,59 and 63-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on 8/24/04 & 9/30/04 have been entered.

Note that the amendment to page 34 (line 12) of the specification incorrectly lists the first SEQ ID NO as SEQ ID NO: 41, versus SEQ ID NO: 40. Appropriate correction is required.

2. The rejections of claim 38 under 35 U.S.C. 101 and under 35 U.S.C. 112, first paragraph, for the claimed invention not being supported by either a specific or substantial asserted utility, are withdrawn due to Applicants' arguments concerning that described in the paragraph bridging pages 8 & 9 of the specification (i.e., as it relates to an effector region being rendered nonfunctional, and its use as a partial inhibitor of parkin).

3. The rejection of claims 32-33, 38-39, 53 & 59 under 35 U.S.C. 102(e) as being anticipated by Tang et al. (WO 01/46256 A2) is withdrawn due to the cancellation or amendment of the claims to "95% identity to the full length PAP1 sequence of SEQ ID NO: 2".

4. Applicants' arguments filed 8/24/04 have been fully considered but they are not deemed to be persuasive.
5. The text of those sections of title 35, U.S. Code not included in this section can be found in a prior Office action.
6. Claim 39 is allowed.
7. Claims 63-65 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No proper antecedent basis nor conception in context with that described within the instant specification at the time of filing Applicants' invention exists for the broader recitation of mix and matching various mutations present into a polypeptide related to SEQ ID NO: 2 (putatively derived from SEQ ID NO: 15; see page 4 of the 6/14/04 response) into a broader concept than the specific polypeptide depicted as SEQ ID NO: 15 (i.e., as it relates to "95% identity to the full length PAP1 sequence of SEQ ID NO: 2"); thereby, constituting new matter.

Lastly, no basis for a mutation at positions #s 148 or 321 of SEQ ID NO: 2 is readily apparent from that described within the instant specification; thereby, further constituting new matter.

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8. Claims 32-33, 38, 53, 59 & 63-65 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons made of record in Paper NOs: 13 (mailed 2/20/03) & 20031217, and as follows.

Similar to that previously made of record, only the “**human**” PAP1 sequences of SEQ ID NOs: 2 & 15 have been described. No written description exists for any PAP1 polypeptides from any *different* species, as encompassed by the current claim language. Second, no written description exists for any allelic variants of the human protein of SEQ ID NO: 2 (except for the specific polypeptide of SEQ ID NO: 15) (i.e., as it relates to the genus recitation of “amino acid sequences of at least 95% identity to... SEQ ID NO: 2”). Therefore, the current claims do not adequately meet the written description requirements under 35 U.S.C. 112, first paragraph, for the reasons extensively made of record; consistent with that held by the courts in *Fiers v. Revel*, *Fiddes v. Baird*, and *Univ. California v. Eli Lilly and Co.*, previously made of record. See MPEP 2163.

9. Claim 32, 38, 53, 59 & 63-65 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the PAP-1 protein of SEQ ID NO: 2, does not reasonably provide enablement for any variant PAP-1 molecules with no distinguishable and assayable functional characteristics, or for “nonfunctional” polypeptides, as currently claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these

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claims, for the reasons made of record in Paper NOs: 13 (mailed 2/20/03) & 20031217, and as follows.

As previously made of record, the specification fails to define the metes and bounds a “specific *interaction* with parkin” entails, and importantly, the claims fail to recite adequate functional and assayable language for the skilled artisan to know “how to use” the instant invention, for the reasons previously made of record; consistent with the teachings of Rudinger previously made of record. Thus, Applicants’ arguments are not persuasive, for the reasons previously made of record.

Likewise, because nowhere in claim 38, nor within the instant specification, is an “effector region” structurally defined, or functionally defined within claim 38, one of skill in the art would not know “how to make and use” such polypeptides wherein “the effector region has been rendered non-functional” without requiring undue experimentation to otherwise determine such, and for the reasons already made of record in the previous Office actions for why structurally and functionally uncharacterized proteins are not reasonably enabled.

10. Claims 32-33, 38, 53, 59 & 63-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons made of record in Paper No: 20031217.

It remains ambiguous what the relative recitation of “capable of a *specific* interaction with parkin” entails, in that it is unknown when something becomes “specific”, versus no longer being specific; especially when no parameters defining what type of “*interaction*” is recited in the claims, as previously made of record.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone number for this Group is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert C. Hayes, Ph.D.
November 10, 2004

ROBERT C. HAYES, PH.D.
PATENT EXAMINER